

Appl. No. 10/519,855  
Amdt. dated: April 7, 2008  
Reply to Office Action of: January 9, 2008

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**Amendments to the Drawings:**

Please replace sheets 1-3 of the drawings with attached Replacements Sheets 1-5.

### **REMARKS/ARGUMENTS**

This application has been carefully reviewed in light of the Office Action dated January 9, 2008. By way of this amendment, new claims 8-11 have been added, and claims 1-7 have been canceled. Sheets 1-3 of the drawings have been replaced with Replacement Sheets 1-5. The specification has been amended to include missing Table 1 and Table 2 as provided on Incorporated Sheets 1-5.

All Incorporated Sheets claim incorporation to PCT/JP03/08305 and WO 2004/003021 as required by MPEP § 1.57, and an English translated copy of the priority document is provided as United States Patent Publication No. 2006/0292160. Replacement Sheets 2 and 4 also claim incorporation to PCT/JP03/08305 and WO 2004/003021 as required by MPEP § 1.57, and an English translated copy of the priority document is provided as United States Patent Publication No. 2006/0292160.

#### **Failure to comply with 37 C.F.R. § 1.821-1.825**

The specification was objected to under the provisions set forth by 37 C.F.R. § 1.821-1.825 for failing to identify sequences in the specification and/or drawings with a sequence identifier. Replacement Sheets 1-5 and Incorporated Sheets 1-5 have been added to further identify the sequence listings.

#### **Objections to the Specification**

The specification was objected to because Tables 1 and 2 were listed but not provided. Incorporated Sheets 1-5 are provided to address this objection and show missing

**Table 1 and Table 2.**

The disclosure referenced five figures, while only three appeared in the application. Replacement Sheets 2 and 4 are provided to amend the drawings to include the missing figures. The inadvertently omitted portion of the drawings can be found on sheets 3 and sheet 5 of the translated application, United States Patent Publication No. 2006/0292160.

The drawings were also objected to for failing to include a figure designation. Replacement Sheets 1, 3, and 5 are provided in response to the Examiner's rejection that the figures did not include a figure designation.

**Rejections under 35 U.S.C. § 112, Second Paragraph**

Claims 1-7 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1-6 have been cancelled in light of this rejection.

**Rejections under 35 U.S.C. § 112, First Paragraph**

Claims 4-7 are rejected under 35 U.S.C. § 112, first paragraph for failing to provide an enabling disclosure for the claimed invention. Claims 1, 4, and 5 are rejected for containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 2-5 are rejected because the claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 1-7 have been cancelled in light of this rejection.

The present invention is directed to a monoclonal antibody falling within the category of human IgM which specifically recognizes HIV-infected cells and induces apoptosis. Using the obtained antibody, it is intended to provide a remedy for patients suffering from HIV-infection, which contains as the active ingredient a human IgM antibody capable of specifically reacting with HIV-infected cells, inducing apoptosis in the infected cells and thus disrupting the cells.

In response to the Examiner's rejections, new claims 8-11 are presented. Claim 8 provides a human IgM monoclonal antibody specifically recognizing HIV-infected cells and including apoptosis of the infected cells, said antibody denominated 2G9 antibody obtainable by a cell strain with an accession No.FERM BP-8378, and comprising sequence a H-chain variable region encoded by the base sequence SEQ ID No.1 and a L-chain variable region encoded by the base sequence SEQ ID No.2. Support for the newly added claims can be found in at least Fig. 1, which shows that the HIV-infected cells are recognized, Fig. 3, which shows that apoptosis is introduced into the HIV-infected cells, the accession number as indicated in the paragraph beginning on page 6, line 3, and SEQ ID Nos. 1 and 2 as indicated in the sequence listing filed with the USPTO on September 14, 2005.

The cell has also been deposited in the International Patent Organism Depository (IPOD) in Japan and is available through accession No. FERM BP-8378. The IPOD complies with the terms of the Budapest treaty, and all restrictions imposed by the

depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent.

The Director is hereby authorized to charge any additional fees or any underpayments which may be required for the above-referenced application to Deposit Account No. 01-0265.

Respectfully submitted,

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File No.: 3348/1

TABLE 1

Base Sequence of  $\mu$ -Chain Variable Region

TGCCCTGGATTCCAAGGCCTATCCACTTGGTGATCAGCACTGAGCACCGAGG  
ATTACCATGGAACTGGGGCTCCGCTGGGTTTCTTGTGTATTTAGAA  
GGTGTCAGTGTGAGGTGCAGCTGGTGGAGTCTGGGGGAGGCCCTGGTCAAG  
CCTGGGGGGTCCCTGAGACTCTCCTGTGCAGCCTCTGGATTACCTTCAGTA  
CTTATAGCATGAACTGGGTCCGCCAGGCTCCAGGGAAGGGGCTGGAGTGGG  
TCTCATCCATTAGTAGTAGTAGTAGTTACATATACTACGCAGACTCAGTGAA  
GGGCCGATTCACCATCTCCAGAGACAAAGCCAAGAACTCACTGTATCTGCAA  
ATGAACAGCCTGAGAGCCGAGGACACGGCTGTGTATTACTGTGCGAGAGAT  
CTCCTTATAGCAGTGGCTGGCCACTGGGGCCAGGGAACCTGGTCACCGTCT  
CCTCA

Base Sequence of  $\kappa$ -Chain Variable Region

CTCAGTCAGGACACAGCATGGACATGAGGGTCCCTGCTCAGCTCCTGGGACT  
CCTGTGCTCTGGCTCCAGATACCAGATGTGACATCCAGATGACCCAGTCT  
CCATCCTCCCTGTCTGCATCTGTAGGAGACAGAGTCACCATCACTTGCCGGG  
CGAGTCAGGGCATTAGCAATTATTTAGCCTGGTATCAGCAGAAACCGGGAA  
AGTTCCTAAACTCCTGATCTATGCTGCATCCACTTTGCAATCAGGGGTCCCA  
TCTCGGTTACAGCGGCAGTGGATCTGGGACAGATTTCACTCTCACCATCAGCA  
GCCTGCAGCCTGAAGATGTTGCAACTTATTACTGTCAAAAGTATAACAGTGC  
CCCGTACACTTTTGGCCAGGGGACCAAGCTGGAGATCAAA

in the amino acid sequences of 2G9 antibody

[illegible]

57

[illegible]

61

G K G L E W V S S I S S S S Y I Y Y A  
GGT AAA GGT NTA GAA TGA GTT TGT TCT ATT TGT TCT TCT TCT TCT TAT ATT TAT TAT GCT  
GCC AAG GGC TGC CAG TGC GTC TGC TGC ATC TGC TGC TGC TCC TAC ATC TAC TAC GGC  
GGA GGA CTT GTA TCA TCA TCA TCA TCA TCA  
GGG GGC CTC GAG TGC TCG TCG TCG TCG TCG TCG TCG  
CTA AGT AGT AGT AGT AGT  
CTC AGC AGC AGC AGC AGC AGC



21

D	S	Y	E	G	R	F	T	I	S	R	D	R	A	K	N	S	L	Y	L
GAT	TCT	GTT	AAA	GCT	GCT	CTT	ACT	ATT	TCT	GCT	GAT	ATT	GCT	AAA	AAT	TCT	TTA	TAT	TTA
GAS	TCC	GTC	AAG	GSC	GTC	TTC	ACC	ATC	TCC	GCT	GAC	GCC	AAG	AGC	TCC	TTC	TAC	TTC	TTC
TCA	GTA	GGA	GGA	GGA	ACA	TCA	GGA	GCA	TCA	GTT	CTT	TCA	GTT	CTT	TCA	GTT	CTT	TCA	GTT
TGG	GTA	GGA	GGA	GGA	AGG	TGG	GGA	GCG	TGG	GTC	CTC	TGG	GTC	CTC	TGG	GTC	CTC	TGG	GTC
AGT						AGT						AGT	CTA	CTA	AGT	CTA	CTA	AGT	CTA
AGC						AGC						AGC	CTG	CTG	AGC	CTG	CTG	AGC	CTG

101

Q H N S L R A S D T A V Y Y C A R D L L  
 CAA ATA AAT TCT TTA GGT GGT GAA GAT ACT GGT GAT TAT TAT TGT GGT GAT TTA TTA  
 CAG ATG ALC TCC TGG GCG GCG GAG GAC AGC GCG GTC TAC TGC GCG GCG GAC TGG TGG  
 TCA CTT CGA GCA ACA GCA GGA GCA CGA CTT CTT  
 TCG CTC CCG GCG ACC GCG GTG GCG GCG CTC CTC  
 AGT GCA CTA CTA  
 AGC CTG CTG CTG

121

I A V A G H W G Q G T L V T V S  
 AAT GCT GTT GGT GAT TGA GGT CAA GGT ACT TTA GTT ACT GTT TCT TCT  
 ATG GCG GTC GCG GCG GAC TGG GCG GAG GGC ACC TTG GTC ACC GTC TCC TCC  
 GCA GTA GCA GGA GGA ACA CTT GGA ACA GTA TCA TCA  
 GCG TGG GCG GCG GCG AGC CTC GTG AGC GTG TCG TCG  
 CTA AGT AGT  
 CTG AGC AGC